JUN - 5 2009

510(k) Summary

Keystone Dental, Inc.
XP1® Angled Abutments

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Keystone Dental, Inc. 144 Middlesex Turnpike Burlington, MA 01803 Telephone: 1 (781) 272-9272 Fax: 1 (781) 272-9972
Official Contact:	Carolyn Bitetti SVP, Quality/Regulatory Keystone Dental, Inc. Direct Line: 781-328-3305 Fax: 781-272-9972 Email: cbitetti@keystonedental.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	XP1 Angled Abutments
Common Name:	Abutment for dental implant
Classification Regulations:	Endosseous dental implant abutment (21 CFR 872.3630), Class II
Product Codes	NHA

DEVICE CLASSIFICATION PANEL

The Classification Panel for these devices is the Dental Products Panel; the devices are reviewed by the Dental Devices Branch.

INTENDED USE

The XP1 Angled Abutment is intended for use in conjunction with the XP1 Dental Implant System in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations. The angled abutment is indicated in cases where angle correction is required.

DEVICE DESCRIPTION

The XP1 15° Angled Abutment is intended to be placed into a dental implant to support prosthetic restorations in partially or fully edentulous mandibles and maxillae. The angled abutment can be used for single or multiple-unit restorations and is intended for cement-retained crowns. The angled abutment is used to correct the prosthetic angulation of implants that are placed off-axis to the occlusal load.

The distal end of the angled abutment has a hex and taper design that engages the mating internal hex and taper of the implant. In addition, the angled abutment has a screw channel with a screw thread at the distal end through which an abutment screw is used to screw the abutment into the implant.

The XP1 Angled Abutment and the abutment screws are machined from titanium alloy (Ti-6AL-4V ELI) conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*

The device is provided non-sterile to the user in medical grade packaging.

EQUIVALENCE TO ORIGINAL CLEARED PRODUCT

Keystone Dental, Inc. has demonstrated that, for the purposes of FDA's regulation of medical devices, the XP1 Angled Abutment is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

Ms. Carolyn Bitetti
Senior Vice President, Quality/Regulatory
Keystone Dental, Incorporated
144 Middlesex Turnpike
Burlington, Masachussets, 01803

Re: K090397
Trade/Device Name: XP1® Angled Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 14, 2009
Received: May 15, 2009

Dear Ms. Bitetti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090397

Device Name: XP1® Angled Abutments

Indications for Use:

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Kevin Mody for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090397

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)